Short Communication

Evidence-Based Practice in Irregular Cornea Patients' Management With Contact Lenses

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ABSTRACT

Contact lenses (CLs) are safe and commonly used method to correct the refractive errors. Rigid gas permeable (RGP) CLs are the first option in visual rehabilitation of patients with irregular cornea, helping to further delay surgical treatment and improve patients' quality of life (QoL). Although, the practice of CLs in patients with irregular cornea must be based on evidence, there is a lack of Clinical Practice Guidelines (CPGs) developed and assessed under high standards as recommended by the Appraisal of Guidelines for Research and Evaluation (AGREE) (http://www.agreetrust.org/). Current fitting guidelines provided by researchers, practitioners, entities or manufacturers, are generally supported with relatively small clinical studies or cohort studies with owner-designs, providing no-objective pathways to conduct the CL fitting that generally require steep learning curve and practitioners with long experience in CL practice. These recommendations are usually not clinically validated to prove the quality and applicability in new clinical scenarios. CL practitioners require evidence-based guidelines and CPGs that include an objective pathway to choose the CL characteristics like design, geometry, material, etc., with clinically validated support of the recommendations to calculate lens parameters such as back optic zone radius, lens diameter and lens geometry. This practice should be based on clinical research with prospective, randomized and well-designed studies (case-control, cohort, or clinical trials studies) that have been developed and assessed under high standards (AGREE). These new evidence-based guidelines or CPGs will not only improve the safety and transparency of CL fitting procedures, but also guarantee the best patient care with less cost to patients with irregular cornea requiring RGP, improving their vision and QoL.

KEY WORDS: Contact Lenses (CL); Rigid Gas Permeable Lenses (RGP); Irregular Cornea; Clinical Practice Guidelines (CPGs); Disposable Lenses; Frequent-Replacement Lenses; Polymethyl Methacrylate (PMMA) Lenses; Silicone Hydrogel CLs.

SHORT COMMUNICATION

Contact lenses (CLs) are a safe and commonly used method to correct the refractive errors (myopia, hyperopic, astigmatism and presbyopia) with an estimated 140 million users worldwide.[1]

The simplest classification of CLs proposes two major categories based on its composition and make.[2] The first being water based, are generally known as hydrogel or soft CLs (with four different groups, based on the water content and surface electric charge[3,4]) and silicone hydrogel CLs (with different classes of silicon lenses).[4] The second, CLs without water are commonly named as rigid gas permeable (RGP) CLs (polymethyl methacrylate (PMMA) lenses, hard CLs, and gas-permeable CL). While the water based CLs are the most frequently prescribed ones, the ones without water are the least prescribed.[5,6]

RGP CLs allow visual acuity rehabilitation in patients with irregular astigmatism, for example in keratoconus patients,[7,8] after complicated corneal refractive surgery,[9] corneal trau-

matism,[10] corneal infection[11] or any other eye surgery as corneal transplantation.[12] Moreover, a special design of RGP CLs with reverse geometry (orthokeratology) are prescribed for a long time for temporary myopia correction[13] and have showed a significant amount of reduction in myopia progression.[14,15]

Now-a-days, a huge variety of CLs with varying materials and designs are available to choose from according to one's preference and requirements. Generally, CLs are prescribed with different replacement wearing plans.[6,16] According to the replacement frequency there are two major options: disposable lenses (intended for single use) and frequent-replacement lenses, where the lenses are cleaned and reused depending upon the expiry dates. Likewise, various types of CLs ranging from daily disposable (for one single use), weekly, fortnightly, monthly, three-six monthly to yearly disposable ones are available to suit the user's requirements and specifications (lens material and other factors).[2] Some reports suggest that RGP CLs are generally fitted without a planned replacement schedule[5] and soft CLs are commonly prescribed with fortnightly or monthly replacement schedule.[17]

CLs can be classified in four main categories: daily wear (worn during the day and removed before sleep), extended wear (worn during the day and while sleeping, for periods no longer than six consecutive nights before their removal), continuous wear (worn for up to 30 consecutive nights without removal), and flexible wear (worn daily with an occasional overnight use or during sleep, for example 2-3 nights per week or during an occasional nap).[2] Daily wear is the most commonly chosen option,[17] except in orthokeratology where overnight wear is the primarily prescribed option.[13]

CL practice in patients with irregular cornea must be evidence-based, which means that the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients must be practised.[18] Preferred practice patterns[19] provide guidance for the pattern of practice and not for the care of a particular individual. Different levels of evidence (Table 1) based on the Scottish Intercollegiate Guideline Network (SIGN)][20] have been proposed and allow to propose different grades of recommendations (Table 2) defined by the Grading of Recommendations Assessment, Development and Evaluation (GRADE).[21-26] Internationally recognized standards have been developed to assess the quality of Clinical Practice Guideline (CPGs) and to guarantee the rigorous development of CPGs. For example, the AGREE II (The Appraisal of Guidelines for Research and Evaluation) (http://www.agreetrust.org/) instrument is a tool, specifically developed for quality assessment of guidelines.[27] Unfortunately, there is not one CL guideline that is assessed under the AGREE requirements now-a-days.

Currently, consensus of experts is the lowest level of evidence but this is commonly used in CLs fitting guidelines, so an increase in research with well-designed studies is necessary to provide sound and evidence-based recommendations to drive CL-practitioners in CL fitting procedure in patients with

Table 1: Levels of Evidence Based on the Scottish Intercollegiate Guideline Network (SIGN).[20]

Level	Type of Evidence
I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
II++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
III	Non-analytic studies (e.g., case reports, case series)
IV	Evidence obtained from expert committee reports or experts´ opinion and/or clinical experiences of respected authorities

Table 2: Grades of recommendations defined by the Grading of Recommendations Assessment, Development and Evaluation (GRADE).[26]

Grade	Recommendation
Good Quality (GQ)	Further research is very unlikely to change our confidence in the estimate of the effect
Moderate Quality (MQ)	Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate
Insufficient Quality (IQ)	Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate Any estimate of the effect is very uncertain

irregular cornea such us keratoconus and other diseases.

The American Optometric Association (AOA) provides a guideline for the care of CL users, based on consensus among experts.[28] Although, this document provides a great reference to CL practitioners, it does not provide specific recommendations to define CL parameters or the range of fitting visits. It mainly focuses on a general description of CL and the most common complications in refractive correction with CL wear, giving limited information about irregular cornea patient management, describing the therapeutic potential of RGP to improve visual acuity and recommending more frequent follow-up visits to these patients. Limited evidence (Level II) supports the different visits (initial or diagnostic visit, dispensing visit and prescribing visit)[29] that confirm the standard CL fitting procedure.

For example, manufactures provide general instructions and recommendations for using their CLs, as well as describing the procedure to calculate the back-optic zone radius (BOZR), lens diameter, lens power, modality of use and replacement, etc. However, most of these recommendations show a lack of evidence behind, especially in describing the CL parameters. Most of these recommendations are based on internal research results, given to the fact that manufacturers are not likely to publish any research/study or instructions in journals which can be accessible to eye care practitioners. These recommendations or guidelines are of paramount importance in RGP CL practice, especially in irregular cornea patients' management with corneal[30] or scleral[31,32] CLs that usually require an experienced CL practitioner.

The BOZR defines soft CL fitting as a simple but much effective procedure that does not require further research. Moreover, manufacturers provide CLs with a limited range of parameters (sometimes with one or two possibilities for example in BOZR or lens diameter). However, it is clearly known that the lens design, material properties, modality of use and replacement, and interaction with lens care system show a significant influence in comfort and user satisfaction.[4] Also, some meta-analyses describe that the risk of an inflammatory complication is mainly related to the material and mode of use.[33] However, with respect to the RGP CLs fitting, the BOZR calculation requires more precision, especially in keratoconus patients with irregular cornea[34] using different methods of fitting the RGP lens (Table 3). In these cases, manufacturers provide

different recommendations to calculate the BOZR (with simple equations or with the support of different CL fitting softwares).[35-41] Different equations to define the BOZR of the first diagnostic lens have been provided by manufacturers or research groups. For example, BOZR could be calculated with Kmean (mm),[42] the horizontal K (mm) – 0.10 mm (recommended by Hecht Contactlinsen), or Kmean (mm) – 0.20 mm (recommended by Menicon, Co., Ltd.),[43] or flat K (mm) – [$\frac{1}{3}$astigmatism (mm)] (proposed by Bausch & Lomb), with different equations depending on the corneal astigmatism,[44] or with the flat K-value directly.[45] Nevertheless, it is uncommon that these guidelines include an analysis of the accuracy or precision of the suggested BOZR compared with the finally fitted BOZR that includes results supported with well-designed studies, for example. So, CL practitioners must refine the calculated BOZR assessing the fluorescein pattern to find the correct lens parameters in each case. Most of the CL practitioners believe that RGP CLs fitting process in keratoconus patients is a challenge that requires an increased number of diagnostic lenses and practitioner time or patient chair time to achieve a final acceptable fit compared with standard RGP or soft CL fitting.[39,46-48] A new way to calculate the first diagnosis RGP parameters closer to finally fitted lens design have been proposed[30] showing a BOZR difference less than 0.10 mm in 75% of cases in a prospective cohort study involving a new sample of keratoconus patients. This new nomogram has the potential to reduce the practitioner and patient chair time in order to achieve a final acceptable RGP lens fit in keratoconus patients.

Recently, scleral RGP CLs have been proposed to be fitted in moderate and advanced keratoconus and irregular cornea patients.[49] However, there is a lack of consensus about the fitting procedures (trial sets characteristics, use of validated nomograms),[31] scleral lens design (fenestrated or non-fenestrated, scleral asymmetry approach),[50] wearing time to avoid or reduce corneal oedema,[51] change in lens vault,[52] lens seal-off management, technology necessary to complete the fitting procedure (corneal topography, tomography, and/or optical coherence tomography),[53] etc. that suggest the need for continued research to clarify scleral RGP indications, fitting procedure, regimen of wear and replacement, and complications management.[31,54] Some reports[55] suggest that scleral RGP lenses should be the lens of choice in patients with irregular cornea for visual rehabilitation and delay or prevent further surgical involvement. Yet, this recommendation is proposed with case report studies in-

Table 3: Different Methods of Fitting Corneal GP Lens in Keratoconus Patients (Fitting Philosophies).

Apical clearance	Apical touch	Three-point-touch
Lens support on the paracentral cornea with clearance of the apex	Lens support and bearing on the corneal apex	Lens support between corneal apex and paracentral cornea, showing a peripheral alignment with slight touch at the apex
Acceptable option with small nipple cones but difficult with advanced keratoconus	Better visual acuity but more risk of corneal abrasions and apical scarring	Most widely-accepted and safest modality of GP CL fitting

volving a few number of patients[32,54] successfully managed with scleral RGP lenses without a comparison with a control group (for example, fitted with corneal RGP CL) in a well-conducted case-control or cohort study. In fact, scleral RGP CLs should be prescribed when other lenses do not provide adequate visual rehabilitation or are not well suitable.[32] Sound fitting guidelines, with objective pathway to choose lens are necessary because scleral RGP CLs fitting requires a steep learning curve, where the practitioner's experience plays a great role in fitting success and more reliable instrumentation to assess scleral and corneal surface is necessary.[31,32]

CONCLUSION

In conclusion, CLs must always be fitted and prescribed by a qualified and competent practitioner after a careful fitting procedure that includes an eye examination to determine whether the CL is suitable for the patient. This will help in minimizing future risk of CL complications.[28] It should be the practitioner's responsibility to prescribe a CL made from a physiologically appropriate material that will induce minimal mechanical impact on the corneal surface while providing the required optical correction to improve the patient's quality of vision and life.[28,56] However, CL practitioners need to be completely aware of evidence-based guidelines and CPGs that include an objective pathway to choose CL characteristics (design, geometry, material, etc.), with clinically validated support of the recommendations to calculate lens parameters (BOZR, lens diameter and lens geometry), based on clinical research with prospective, randomized and well-designed studies (case-control, cohort, or clinical trials studies), that should be developed and assessed under high standards (AGREE). These new evidence-based guidelines or CPGs will not only improve the safety and transparency of CL fitting procedures, but also guarantee the best patient care with less cost to patients with irregular cornea requiring RGP, improving their vision and quality of life (QoL) significantly.

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